

## **SUMMARY OF THE ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING DECEMBER 17, 1999**

The newly appointed Environmental Laboratory Advisory Board (ELAB) met on Friday, December 17, 1999, at 8 a.m. Eastern Standard Time (EST) following the Fifth NELAC Interim Meeting in Washington, DC. The meeting was opened by its Designated Federal Officer (DFO), Mr. David Friedman of the United States Environmental Protection Agency (USEPA), pending the election of a chairperson. Thereafter, the meeting was led by its newly elected chair, Dr. J. Wilson Hershey of Lancaster Laboratories, Inc. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The meeting agenda is given in Attachment C. A summary of the current status of ELAB recommendations is given in Attachment D.

### **INTRODUCTION**

The meeting was called to order by Mr. Friedman. Following a brief introduction of board members, Mr. Friedman called for nominations for chair. A member of the board nominated Dr. Hershey and the nomination was seconded. There being no additional nominations for chair, the nominations were closed. Dr. Hershey was elected by a unanimous vote of the board members in attendance and then assumed leadership of the meeting. Dr. Hershey explained that ELAB, a USEPA-sponsored private sector advisory committee established under the Federal Advisory Committee Act (FACA), had been rechartered the previous week with only three returning members. He noted that the fresh perspective offered by the new membership is exciting but that the recent rechartering had allowed little time for preparation for the meeting. There being no additions to the draft agenda prepared for the meeting by Mr. Friedman, Dr. Hershey proceeded to the next order of business.

### **REVIEW OF OUTSTANDING RECOMMENDATIONS**

The board reviewed the status of ELAB recommendations (see Attachment D) and assigned a priority of "High," "Medium," "Inactive," or "Completed" to each outstanding recommendation. The prioritization of outstanding recommendations and any pursuant ELAB discussion is summarized below:

- **ELAB Recommendation 2A (2/6/97)** - NELAC scope of accreditation - ELAB "Inactive" priority maintained
- **ELAB Recommendation 2B (2/6/97)** - Proficiency Testing (PT) sample issues - ELAB priority changed to "Completed"
- **ELAB Recommendation 4 (2/6/97)** - Information to be included in NELAC national database

In discussion of this issue, Mr. Jerry Parr referenced the report by Dr. Ken Jackson (chair of NELAC) to ELAB at the Fifth NELAC Annual Meeting as reflected in the June 30, 1999, ELAB meeting minutes. At that time, Dr. Jackson noted that the NELAC National Database *ad hoc* Committee would link the database fields of "Accrediting Authority" and "assessor body," and that the "assessor body" field

would list pertinent functions. It was also noted that a related database issue had been raised in the ELAB Open Forum on December 16, 1999. Further discussion of the issue was deferred to discussion of Open Forum issues later in the meeting.

- **ELAB Recommendation 5A (2/6/97)** - Consistent implementation of performance based measurement systems (PBMS) - ELAB “High” priority maintained

Dr. Jackson, speaking on behalf of the NELAC Board of Directors, informed ELAB that NELAC has done all it can do until USEPA assumes a PBMS position. It was suggested that ELAB maintain a position on PBMS to gather information and make recommendations to USEPA. It was moved, seconded, and approved unanimously that

**ELAB establish a subcommittee to revisit PBMS issues and develop a recommended course of action for the consistent implementation of PBMS.**

The PBMS subcommittee will be chaired by Mr. Harry Gearhart and will include Mr. Parr, Mr. Mark Marcus, and Ms. Elaine LeMoine.

- **ELAB Recommendation 5B (2/6/97)** - Training in implementation of PBMS for state laboratory inspectors - ELAB “High” priority maintained

This issue was referred to the PBMS subcommittee.

- **ELAB Recommendation 6 (7/28/97)** - Preparation of PT sample design criteria for use by the Proficiency Testing Oversight Body (PTOB) -ELAB “Inactive” priority maintained
- **ELAB Recommendation 9A (7/28/97)** - Development of scope of accreditation and PT sample design consistent with PBMS

This issue was deferred to the PBMS subcommittee.

- **ELAB Recommendation 9C (7/28/97)** - Monitoring of discrepancy between NELAC PT program design and NELAC scope of accreditation - ELAB “Inactive” priority maintained
- **ELAB Recommendation 10 (7/28/97)** - Consistency between NELAC Standards and USEPA’s PT Externalization program - Although originally marked “Completed,” this issue was deemed still active and tabled for later discussion in an ELAB teleconference.
- **ELAB Recommendation 13 (7/28/97)** - Reliability of published USEPA methods - ELAB “High” priority maintained - assigned to the PBMS subcommittee.
- **ELAB Recommendation 14 (7/28/97)** - Achievability of published USEPA regulatory measurement requirements - ELAB “High” priority maintained - assigned to the PBMS subcommittee.
- **ELAB Recommendation 15 (7/28/97)** - Performance Based Measurement System (PBMS) versus PB Method - ELAB “High” priority maintained

This issue was referred to the PBMS Subcommittee.

- **ELAB Recommendation 19 (7/28/97)** - Conflict of interest between public and private sector laboratories

Although originally marked “High” priority, this issue was deemed “Completed” per Dr. Jackson’s June 30, 1999, report to ELAB as reflected in the June 30, 1999, meeting minutes.

- **ELAB Recommendation 22 (7/28/97)** - Consistency between regulations promulgated by USEPA Program Offices and NELAC Standards - ELAB “High” priority maintained

It was moved, seconded, and approved unanimously that

**ELAB establish a subcommittee to examine USEPA regulatory actions, Quality Control (QC) standards, PT program requirements, and methods development for consistency with NELAC Standards and diligently pursue action on the matter.**

The Regulatory Consistency subcommittee will be chaired by Ms. Zonetta English and will include Ms. Barbara Burmeister, Ms. Marlene Moore, Mr. Parr, Mr. Gearhart, and Mr. David McClure.

ELAB Recommendation 22 generated considerable discussion of recently promulgated Safe Drinking Water Act (SDWA) regulations (64 FR 67450). Dr. Jackson, speaking for the NELAC Board of Directors, noted that the July 1999 NELAC Standards were presented unambiguously at the Fifth NELAC Annual Meeting but with little input from USEPA’s Office of Water. He suggested a cooperative effort with the Office of Water. Ms. Burmeister, chair of the NELAC Proficiency Testing (PT) Committee, noted that the PT Committee did have communication with the Office of Water during the promulgation of the recent SDWA regulations. A participant noted that there is a Memorandum of Understanding between NELAC and the Office of Water and suggested that the subcommittee investigate whether the Memorandum of Understanding might be reaffirmed. Members of ELAB noted that Ms. Cynthia Dougherty of USEPA had been the signatory on the original memo and indicated that the subcommittee would investigate. It was suggested that the subcommittee gather specific examples of instances in which USEPA *regional* regulatory activities are not consistent with NELAC implementation. A member of ELAB asked whether it is appropriate for ELAB to comment on a regulation stating that it is inconsistent with NELAC implementation. It was agreed that it is within the scope of ELAB’s charter to make such a comment directly to the agency’s Deputy Administrator.

- **ELAB Recommendation 23 (1/16/98)** - Advisory appendix to address the issue of due process for laboratories - ELAB “High” priority maintained - assigned to Ms. English.

Participants suggested that this issue should be maintained by ELAB as a high-priority issue. Although detailed procedures for due process vary from state to state, the NELAC Accreditation Process (AP) Standard may, nevertheless, outline those issues of due process important to the laboratory community. Ms. English, a former member of the NELAC AP Committee, noted that she did not think the committee had ever received an official communique on this issue from ELAB. She accepted the responsibility to communicate the issue to the AP Committee. The issue was tabled pending a response from the NELAC AP Committee.

- **ELAB Recommendation 24 (1/16/98)** - Representation of all NELAC stakeholders during consideration of inclusion of sampling in NELAC Standards - ELAB “Inactive” priority maintained - combined with Issue 41
- **ELAB Recommendation 26 (1/16/98)** - Report from USEPA on the Agency’s action regarding PBMS and how it relates to the NELAC Quality Systems (QS) Standard

This issue was referred to the PBMS Subcommittee.

- **ELAB Recommendation 27A (7/1/98)** - Streamlining of USEPA’s Office of Water methods approval process as an intermediate step to PBMS

This issue was referred to the PBMS Subcommittee.

- **ELAB Recommendation 28 (7/1/98)** - Accrediting Authority Review Board (AARB) issues - ELAB “Medium” priority maintained

It was suggested that ELAB appoint a liaison to the AARB to assist the AARB in preparation of annual reports. The justification given for this suggestion was a request from the Accrediting Authorities (AAs) for private sector representation on the AARB. In response, it was noted that such an arrangement would violate FACA rules unless the AARB were a subgroup of ELAB. After moderate discussion of the issue, it was moved, seconded, and approved unanimously that

**ELAB continue to gather information on AARB issues from the NELAC Program Policy and Structure (PP&S) Committee and from the AARB for discussion at a future ELAB teleconference.**

- **ELAB Recommendation 29 (7/1/98)** - USEPA/Department of Transportation (DOT) sample transport regulatory consistency issues - ELAB “High” priority maintained

Mr. Friedman reported that he is awaiting a response from DOT regarding their shipping regulations. He could not give a firm date by which he will receive their response. Mr. Friedman noted that if DOT will not change their shipping regulations, then USEPA must reconsider their sample preservation requirements.

- **ELAB Recommendation 31 (7/1/98)** - Third-party assessor subcommittee - ELAB “High” priority maintained

In discussion of third-party assessor issues, it was noted that various NELAC committees are concerned with the technical competence of third-party assessors and that the committees are interested in private sector input on the requirements for third-party assessors. After moderate discussion of the issue, it was moved, seconded, and approved unanimously that

**ELAB re-establish a subcommittee to evaluate minimum credentials for third-party assessors.**

The Third-party Assessor Credentialing subcommittee will be chaired by Mr. Marcus and will include Mr. Tom Peel and Ms. Roxanne Robinson.

- **ELAB Recommendation 32 (7/1/98)** - On-site assessment checklist recommendations - ELAB “High” priority maintained - assigned to Mr. Parr

The ELAB Laboratory Assessment Subcommittee completed a report for submission to NELAC and the NELAC On-site Assessment (OA) Committee. In discussion of this issue from the floor, a representative from the OA Committee confirmed that the committee has seen ELAB's recommendations but noted that the OA Committee will not be preparing technology checklists. It was suggested that ELAB review their recommendations in light of the OA QS checklist recently posted on the NELAC Internet site. Mr. Parr accepted the responsibility to review the ELAB Laboratory Assessment Subcommittee's recommendations on checklists and prepare them as a revised ELAB report for ELAB review and submission to NELAC and the OA Committee.

- **ELAB Recommendation 33 (7/1/98)** - Conflict of interest between public and private sector laboratories - ELAB "Inactive" priority maintained - linked to Recommendation 23 assignment to Ms. English
- **ELAB Recommendation 34 (7/1/98)** - Rights, responsibilities, and obligations of laboratories and AAs - ELAB "Inactive" priority maintained - linked to Recommendation 23 assignment to Ms. English
- **ELAB Recommendation 35 (1/14/99)** - Outreach to laboratory associations through the NELAC Webpage - Designated "Completed"
- **ELAB Recommendation 36 (1/14/99)** - Flow of information to NELAC committees through NELAC Membership and Outreach (M&O) Committee - ELAB "Inactive" status maintained
- **ELAB Recommendation 37 (1/14/99)** - NELAC Standards to contain only essentials for data quality; small laboratory issues - ELAB "Inactive" status maintained
- **ELAB Recommendation 38 (1/14/99)** - Definitions of critical terms prior to defining the accreditation process for non-fixed laboratories - ELAB "High" priority maintained - jointly assigned to Mr. Allen Verstuyft and Mr. McClure
- **ELAB Recommendation 39 (1/14/99)** - Expanded availability of PT samples for matrices other than water - ELAB priority changed to "Completed"

Ms. Burmeister informed ELAB that the NELAC PT Committee has learned that the USEPA database currently accepting PT provider data is limited to water. Consequently, there is no oversight for any PT programs other than the Water Supply/Water Pollution (WS/WP) PT series. Although ELAB did not modify its assessment of Recommendation 39 as "Completed," it was agreed that a new recommendation to USEPA is in order. After moderate discussion, it was moved, seconded, and approved unanimously that

**ELAB investigate an expanded PT scope of accreditation. To this end, ELAB will request a report on this issue from the NELAC PT Committee at the Sixth NELAC Annual Meeting.**

- **ELAB Recommendation 40 (1/14/99)** - Time line recommendation - ELAB priority changed to "Completed".

- **ELAB Recommendation 41 (12/10/98)** - Continued work on field measurement Standards - ELAB “High” priority maintained
- **ELAB Recommendation 42 (3/1/99)** - Laboratory inspections performed according to NELAC Standards, no separate category for interim accreditation status in national NELAC database. ELAB priority changed to “Completed”.

It was noted that the use and designation of “Interim” for NELAP accreditation status, particularly on accreditation certificates, had been raised as an issue of continuing concern in the ELAB Open Forum on December 16, 1999. Members of ELAB noted that they would like to receive a report from the first 11 approved AAs no later than March or April 2000 regarding how they propose to handle the issue of interim status on NELAP accreditation certificates. Dr. Jackson, speaking on behalf of the State of New York as an approved AA, noted that the Accrediting Authority Group meets biweekly by teleconference. He indicated that he would make the interim status issue a high priority at the next teleconference.

## **REVIEW OF JUNE 30, 1999, ELAB RECOMMENDATIONS**

The board briefly reviewed recommendations arising from their June 30, 1999, meeting in Saratoga Springs, NY. Mr. Parr noted that a Scope of Accreditation Subcommittee had been approved at that time with the goal of providing a consensus recommendation to ELAB on scope of accreditation, including relative priority of elements in the database, for NELAC consideration for implementation. The subcommittee proposed to provide this recommendation by reviewing pertinent documents and interviewing stakeholders from laboratories, state agencies, USEPA, and individuals knowledgeable about the topic of scope of accreditation. The ELAB charter expired, however, before the subcommittee was able to accomplish their goal. Consequently, Mr. Parr proposed reinvigorating the Scope of Accreditation Subcommittee with the goal of reporting to ELAB by March 2000. In response, Ms. Jeanne Mourrain, NELAC Director, reminded board members of the March 1, 2000, deadline for submittal of comments to be considered by NELAC committees at the Sixth NELAC Annual Meeting. It was moved, seconded, and approved unanimously that

### **ELAB re-establish the Scope of Accreditation Subcommittee.**

The subcommittee will be co-chaired by Mr. Parr and Ms. Moore and will include Ms. LeMoine, Ms. Connie Hull, Dr. Kircher, Mr. George Avery, and Mr. Dan Hickman.

It was moved, seconded, and unanimously approved that the remainder of the June 30, 1999, recommendations be addressed in a future ELAB teleconference.

## **OPEN FORUM ISSUES**

Members of the board enumerated issues that were raised in the ELAB Open Forum on December 16, 1999. Their disposition is summarized as follows:

- Need to ensure consistency and coordination between USEPA regulations, guidance, and policies and the NELAC Standards

This issue was deferred to the ELAB Regulatory Consistency Subcommittee.

- Need to examine the structure of NELAC Fields of Testing for appropriateness to present and future use, particularly in anticipation of PBMS implementation

This issue was deferred to the ELAB Scope of Accreditation Subcommittee.

- Need to encourage the implementation of PBMS

This issue was deferred to the ELAB PBMS Subcommittee.

- Suggestion that ELAB continue to include laboratory assessor training issues on its agenda

This issue was deemed complete.

- Need to address integration/reconciliation of International Standardization Organization (ISO) guides with the NELAC Standards and to draw ISO expertise into ELAB via an organization, individual, or subcommittee

It was noted that, although NELAC committees are reviewing ISO document 17025 and will incorporate ISO guidelines into their NELAC Standards over a period of time, the NELAC community does not have a complete grasp of the ISO system. Participants were in general agreement that the NELAC community is in need of education and that the greatest knowledge of the ISO system comes from the private sector. It was suggested that ELAB provide the Global Institute of Environmental Scientists (GIES) with ISO information to be incorporated into the GIES pilot assessor training program. After considerable discussion of this issue, it was moved, seconded, and approved unanimously that

**ELAB establish a subcommittee to identify inconsistencies between the ISO and NELAC processes and to review assessor training materials from the first pilot training course for inclusion of ISO information.**

It was agreed that Mr. Peter Spath brings years of ISO experience to ELAB. Mr. Spath will chair the subcommittee. The subcommittee will include Mr. McClure and Ms. Robinson. Possible outputs include a gap analysis of NELAC and ISO standards, and review of NELAC laboratory assessor training materials for consistency with ISO specifications.

- Need to identify viable mechanisms for all stakeholders to participate in NELAC decision-making process

It was agreed that this issue had been reconciled.

- Suggestion that ELAB re-establish the its subcommittee on QC samples

After brief discussion of this issue, it was moved, seconded, and approved unanimously that

**ELAB re-establish the QC Standard Subcommittee.**

It was agreed that Mr. Parr would chair the subcommittee and Ms. Loring and Ms. Watson would also work on the subcommittee.

- Suggestion that NELAC national database be expanded from reporting current laboratory status to including historical information and other information that will make it more useful

Much of the discussion of this issue focused on financial considerations necessary for the maintenance of the national database. A board member suggested that, rather than allowing funding to drive the design of the database, benefit to NELAC should drive the design and decide the funding necessary to implement it. Consequently, it was suggested that the NELAC National Database Committee should first prioritize the database functionality needs. After considerable discussion of the issue and its complexity, it was moved, seconded, and approved unanimously that

**the national database issue be deferred with high priority for an ELAB teleconference to be held by mid-February 2000 at the latest.**

- Suggestion that ELAB explore additional financial resources, especially for maintaining the national database, such as state laboratory associations or a commercial Internet site with advertising revenue

This issue was deemed to be outside the scope of ELAB. It was noted, however, that the NELAC Board of Directors has directed the NELAC Transition Committee to quickly develop a plan for securing NELAC support within USEPA.

- Suggestion that ELAB consider developing a “white paper” on the advantages and disadvantages of a national laboratory accreditation program

It was noted that such a position paper could be used as a tool for exploring additional financial resources. An attendee reminded the board that one of NELAC’s predecessors, the National Environmental Laboratory Accreditation Coalition, made up of over 800 participants with a broad-based membership, produced a unified position paper. It was suggested that this position paper could be used as a starting point for a similar ELAB position paper. It was moved, seconded, and approved unanimously that

**ELAB establish a subcommittee to review all resources available to them and prepare and publish a “white paper” on the advantages and disadvantages of national laboratory accreditation. The paper will represent the perspectives of all laboratory accreditation stakeholders and will constitute an effort totally independent of NELAC.**

The National Laboratory Accreditation Issues subcommittee will be chaired by Mr. Jim Kendzel and will include Mr. Parr, Mr. McClure, and Ms. Lynn Bradley.

- Need to review process for developing PT acceptance limits under the current privatized PT program, particularly with respect to the regulatory requirements being supported

This issue was assigned to the NELAC PT Committee to be included in their July 2000 report to ELAB.

- Need to review the use and designation of “Interim” accreditation status, particularly on NELAP accreditation certificates



This issue was addressed in discussion of ELAB Recommendation 42 and awaits a report from the State AA Subcommittee.

## **CONCLUSION**

Since the allotted time for the meeting was drawing to a close, it was decided that Mr. Friedman will schedule a teleconference for February 15, 2000, from 1 p.m. to 4 p.m EST, to discuss the status of high-priority items remaining among ELAB recommendations. This meeting was adjourned at 11:30 a.m. EST.

**ACTION ITEMS**  
**ENVIRONMENTAL LABORATORY ADVISORY BOARD**  
**DECEMBER 17, 1999**

<b>Recom #</b>	<b>Item No.</b>	<b>Action</b>	<b>Date to be Completed</b>
5A	1.	PBMS subcommittee (H. Gearhart, chair; E. LeMoine, M. Marcus, J. Parr) will address assigned issues.	
22	2.	Regulatory Consistency subcommittee (Z. English, chair; B. Burmeister, H. Gearhart, D. McClure, M. Moore, J. Parr) will address assigned issues.	
31	3.	Third Party Assessor Credentialing subcommittee (M. Marcus, chair; T. Peel, R. Robinson) will address assigned issues.	
48	4.	Scope of Accreditation subcommittee (J. Parr & M. Moore co-chairs; G. Avery, Dan Hickman, C. Hull, C. Kircher, E. LeMoine) will address assigned issues.	
44	5.	NELAC-ISO Consistency subcommittee (P. Spath, chair; C. McClure, R. Robinson) will address assigned issues.	
49	6.	QC Standards subcommittee (J. Parr, chair; D. Loring, K. Watson) will address assigned issues.	
46	7.	National Laboratory Accreditation Issues subcommittee (J. Kendzel, chair; L. Bradley, D. McClure, J. Parr) will address assigned issues.	
23	8.	Ms. Zonetta English will communicate to the NELAC Accreditation Process Committee ELAB's recommendation that an advisory appendix be written to address the issue of due process for laboratories.	
28	9.	ELAB will continue to gather information on AARB issues from the NELAC Program Policy and Structure (PP&S) Committee and from the AARB for discussion at a future ELAB teleconference.	
29	11.	Mr. David Friedman will reported to ELAB when he receives a response from DOT regarding their shipping regulations.	Ongoing

<b>Recom #</b>	<b>Item No.</b>	<b>Action</b>	<b>Date to be Completed</b>
32	12.	Mr. Jerry Parr will review the ELAB Laboratory Assessment Subcommittee's recommendations on checklists and prepare them as a revised ELAB report for ELAB review and submission to NELAC and the OA Committee.	
39	13.	ELAB will investigate an expanded PT scope of accreditation. To this end, ELAB will request a report on this issue from the NELAC PT Committee at the Sixth NELAC Annual Meeting.	
42	14.	ELAB will request a report from the AA Group regarding how they propose to handle the issue of interim status on NELAP accreditation certificates.	4/1/2000
	15.	ELAB will review NELAC national database reporting information issues.	

**PARTICIPANTS  
ENVIRONMENTAL LABORATORY ADVISORY BOARD  
DECEMBER 17, 1999**

<b>Name</b>	<b>Affiliation</b>	<b>Address</b>
Hershey, J. Wilson      Chair	Lancaster Laboratories, Inc.	T: (717) 656 - 2300 F: (717) 656 - 0450 E: jwhershey@lancasterlabs.com
Friedman, David      DFO	USEPA	T: (202) 564 - 6662 F: (202) 565 - 2432 E: friedman.david@epa.gov
Bigmeat, John (via telephone)	Cherokee Nation Water Treatment Plant	T: (828) 497 - 3005 F: (828) 497 - 3268 E: johnbigm@dnnet.net
DeGaetano, Robert	ChemData Professionals	T: (813) 975 - 1664 F: (813) 972 - 5110 E: labguru@mindspring.com
English, Zonetta	Louisville and Jefferson County Metro Sewer District	T: (502) 540 - 6706 F: (502) 540 - 6779 E: english@msdlouky.org
Gearhart, Harry	DuPont Engineering.	T: (405) 372 - 7575 F: E: harry.l.gearhart@usa.dupont.com
Hull, Connie	Kansas City Water Services	T: (816) 454 - 7600 F: (816) 454 - 6488 E: connie_hull@kcmo.org
Kendzel, Jim (via telephone)	NSF International	T: (734) 769 - 5184 F: (734) 769 - 0109 E: kendzel@nsf.org
LeMoine, Elaine	Perkin Elmer	T: (203) 761 - 2771 F: (203) 761 - 2887 E:
Marcus, Mark (via telephone)	Waste Management Federal Services of Hanaford, Inc.	T: (509) 373 - 3026 F: (509) 372 - 0456 E: mark_f_marcus@rl.gov
McClure, David	OMNI Engineering Services & OMNI Test Laboratories	T: (503) 643 - 3788 F: (503) 643 - 3799 E: davidmclure@omni-test.com
Parr, Jerry	Catalyst Info. Resources, L.L.C.	T: (303) 670 - 7823 F: (303) 670 - 2964 E: catalyst@eazy.net
Peel, Tom (via telephone)	Geosyntec	T: (561) 995 - 0900 F: (561) 995 - 0925 E: tomp@geosyntec.com
Spath, Peter	Eastman Kodak	T: (716) 588 - 0801 F: (716) 722 - 4406 E: pspath@kodak.com

**PARTICIPANTS (CONTINUED)**  
**ENVIRONMENTAL LABORATORY ADVISORY BOARD**  
**DECEMBER 17, 1999**

Verstuyft, Allen (absent)	Chevron Research and Technology	T: (510) 242 - 3403 F: (510) 242 - 1792 E: awve@chevron.com
Tatsch, Gene (Contractor Support)	Research Triangle Institute	T: (919) 541-6930 F: (828) 628-0659 E: cet@rti.org
Greene, Lisa (Contractor Support)	Research Triangle Institute	T: (919) 541-7483 F: (919) 541-7386 E: lcg@rti.org

**Environmental Laboratory Advisory Board (ELAB)**

**December 17, 1999  
8:00 a.m. - 12:00 p.m.**

**J.W. Marriott Hotel  
Washington, DC**

**Agenda**

Introduction of Members

Election of Chairperson

Review of outstanding recommendations

Review of Issues identified in Open Forum on 12/16/99

Identification of other issues to be considered by Board

Discussion of Board Action Plan

Next Steps and schedule next meeting

Meeting Closure

**Attachment D****LISTING & STATUS OF ELAB RECOMMENDATIONS****Priorities Defined****HIGH - activity is an urgent matter; an ELAB member has been assigned to monitor progress on the recommendation****MEDIUM - activity is of importance to ELAB; ELAB will monitor progress periodically****INACTIVE - activity either has been dealt with under another recommendation or is no longer applicable****COMPLETED - recommendation has been addressed or acted upon by ELAB or another organization**

<b>Rec. #</b>	<b>Date of Rec</b>	<b>Recommendation</b>	<b>Notes</b>	<b>Action</b>	<b>ELAB Priority</b>
1	2/6/97	The GLP Subcommittee will present a final report and recommendations at the next ELAB meeting in July, 1997.		ELAB completed report. Awaiting response from EPA EMMC Policy Council. Letter received from EPA/OECA 4/15/99; forwarded letter to NELAC.	COMPLETED
2A	2/6/97	The issue of how to define the basis for NELAC accreditation is of concern to the laboratory community and should continue to be addressed jointly by the NELAC Committees on Proficiency Testing and Program Policy and Structure. ELAB participation in the effort will be the responsibility of Mr. Coyner and Ms. Moore, who are members of the Proficiency Testing and Program Policy and Structure Committees, respectively.		Recommendation remains open. Awaiting action from NELAC PT and PPS committees and ELAB members.	INACTIVE
2B	2/6/97	ELAB recommends to EMMC and the NELAC Board of Directors, regarding proficiency testing, that the goal of the NELAC PT program should be to provide full-volume, real-world samples, keeping in mind considerations of practicality and cost.		Recommendation remains open. Awaiting action from NELAC Board and EMMC Policy Council	COMPLETED
2C	2/6/97	ELAB recommends to EMMC and the NELAC Board of Directors, regarding proficiency testing, that the USEPA serve as the oversight body for the PT program, with the necessary resources and commitment to improve the current system. Alternatively, ELAB recommends that the oversight body be another government organization and that steps be taken to ensure a smooth transition.		Completed - NIST to serve as PTOB	COMPLETED

Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
3	2/6/97	ELAB will recommend to the NELAC Board of Directors that the Program Policy and Structure Committee address the issue of how to recognize an appropriate role for Native American Tribal Nations in NELAC		Recommendation remains open. Awaiting action from NELAC Board and PPS committee	MEDIUM
4	2/6/97	With regard to the role of private-sector accrediting bodies in NELAC, ELAB will recommend to the NELAC Board of Directors that the NELAC national database include publicly available information describing the functions performed by individual private organizations for specific State programs		Recommendation remains open. Awaiting action from NELAC Board	HIGH
5A	2/6/97	ELAB recommends to the EMMC and the NELAC Board of Directors that USEPA's programs and Regions and the States work to implement PBMS consistently.		Recommendation remains open. Awaiting Action from NELAC Board and EMMC Policy Council.  Assigned to PBMS subcommittee 12/17/99	HIGH
5B	2/6/97	ELAB recommends to the EMMC and the NELAC Board of Directors that training in implementation of PBMS is needed for State Laboratory inspectors		Recommendation remains open. Awaiting action from NELAC Board and EMMC PC.  Assigned to PBMS subcommittee 12/17/99.	HIGH
5C	2/6/97	ELAB recommends to the EMMC and the NELAC Board of Directors that a representative from the EMMC Work Group on PBMS work with the ELABG PBMS Subcommittee in the future		L. Williams, L. Autry, and B. Runyon, all from EPA, participated on the PBMS subcommittee	COMPLETED
6	7/28/97	ELAB recommends that EPA prepare a working set of PT sample design criteria which meet Program Office requirements to be used by the Proficiency Testing Oversight Body (PTOB) to include, at a minimum, concentration, interferences, media.	NELAC is working with EPA/EMMC to develop specifications for proficiency testing (PT) sample design criteria for use by the Proficiency Testing Oversight Body (PTOB). EPA is also working with NIST to develop a draft of the standard. The draft is currently awaiting response from EPA	Recommendation remains open. Criteria have been developed for the Water Pollution (WP) and Water Supply (WS) samples. ELAB wishes to reinforce that the recommendation is still important. Awaiting action from EPA Program offices for criteria other than WP and WS. Will be addressed under #39.	INACTIVE



Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
7	7/28/97	ELAB recommends that NELAC/NIST/EPA develop a protocol which can be used by the PTOB, through review and analysis of data, to assure program equivalency among PT providers. (See attached paper by Dan Tholen for starting point.) ELAB further recommends that this protocol be finalized as soon as possible to ensure the integrity of this program	The NELAC PT committee has worked with NIST and EPA to produce a draft standard for PTOB to assure equivalence among PT providers. An overview of the draft document, Handbook 150-xx, was given by NIST in the NIST Open Meeting on the morning of January 16, 1998. NIST reviewed Handbook 150-xx and requested public comments by March 15, 1998. Members of the ELAB were impressed with the draft document and the cooperation with NIST and EPA	Completed. ELAB sent a letter to EPA and NIST complimenting them on their work to date on developing Handbook 150-xx	COMPLETED
8	7/28/97	ELAB recommends to NELAC that the periodic PT studies occur at fixed times throughout the year. ELAB further recommends that initial and remedial PT samples may be obtained outside this schedule	ELAB has formerly recommended to NELAC that periodic PT studies be conducted at fixed times throughout the year. The problems crated by labs not being able to receive or reinstate accreditation due to scheduling were discussed. ELAB is concerned about the effect of having only two opportunities per year for obtaining PT samples, will have on the accreditation process, both initial and remedial. recommends that ensure that the PT system not delay the laboratory accreditation process by more than thirty cays.	PT standards have been revised to indicate that accrediting authority may set the schedule. Remedial samples may be obtained	COMPLETED

Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
9A	7/28/97	ELAB recommends that the long range goal of NELAC be to develop a consistent approach to both scope of accreditation and PT program sample design, which recognizes the needs of the laboratories, the primary accrediting authorities, and the Agency, particularly with regard to performance based methods, similar technologies, and analytical capabilities.	The goal to develop a consistent scope of accreditation and PT programs has been endorsed by the NELAC PT Committee. ELAB discussed the need for the scope of accreditation and PT programs to address performance based measurement systems (PBMS), similar technologies, and analytical capabilities. It was suggested since PBMS is still under development by EPA, NELAC should monitor progress in the program but avoid any delays in the implementation of the NELAC PT program	Recommendation remains open. Awaiting action from NELAC PT and PPS committees. New ELAB subcommittee addressing scope of accreditation issue.  Assigned to PBMS subcommittee 12/17/99	ACTIVE
9B	7/28/97	ELAB recommends that the PTOB, during implementation of the PT program, require that each PT provider record and report PT results to both the accrediting authority and the PTOB on a method basis, by matrix and analyte.	NELAC is awaiting EPA specifications for reporting by method, matrix, and analyte. ELAB will recommend that the Proficiency Testing Oversight Body (PTOB) require that each PT provider record and report PT results to both the accrediting authority and to the PTOB to meet the EPA specifications.	Completed. The PT committee's proposed standards for program/matrix/analyte was adopted by NELAC.	COMPLETED
9C	7/28/97	ELAB recommends to NELAC that a task group monitor the impact on implementation of the discrepancy between PT program design and the scope of accreditation.		Recommendation remains open. Awaiting action from NELAC once program is operational.	INACTIVE
10	7/28/97	ELAB recommends that there is consistency between NELAC Standards and the EPA's PT Externalization program.	NELAC is working closely with EPA and EMMC to insure that NELAC standards are consistent with EPA's PT externalization program. A PT Committee meeting with EMMC in September 1998 indicated close cooperation in developing consistent PT standards.	Issue to be revisited in subsequent meetings.	ACTIVE
11	7/28/97	ELAB recommends that the proposed PT standards (including the Appendices) be adopted as presented.	The recommendation to adopt the proposed PT standards has been accomplished.	Completed.	COMPLETED

Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
12	7/28/97	<p>ELAB recommends to NELAC that the GLP decisions and the NELAC timeline be decoupled.</p> <p>ELAB further recommends that the GLP subcommittee report to the ELAB at the Interim Meeting with three options including a) status quo; b) Options 1+3+5; and c) lab accreditation.</p> <p>ELAB further recommends that ISO Guide 25 be explicitly considered to understand the value it offers to the GLP process.</p> <p>ELAB further recommends that the NELAC process be evaluated to identify the value added, if any. EPA will provide language to clarify that the NELAC Constitution and Bylaws reflect that decision-making and implementation of the GLP Program will continue as an exclusively federal program.</p> <p>The goal of this activity is to provide information to OECA and OPPTS management for a decision regarding the direction of the GLP program.</p>	Addressed in the GLP report.	Completed. GLP report has been forwarded to EPA - awaiting response from EMMC Policy Council.	COMPLETED
13	7/28/97	ELAB recommends that before EPA promulgates a regulation, it must demonstrate and document that NQOs are achievable using available measurement technology. Recommendations modified to: ELAB recommends that before EPA publishes a method, whether in regulation or guidance, the method must be demonstrated reliable for its stated use.	This recommendation was reconsidered and determined to need modification (see above). This issue was brought to the attention of the EPA Acting Deputy Administrator Peter Robertson on Marcy 9, 1999, at which time he agreed to pursue this issue with the EMMC Policy Council.	<p>Recommendation remains open. Awaiting response from Deputy Administrator.</p> <p>Assigned to PBMS subcommittee 12/17/99.</p>	HIGH
14	7/28/97	ELAB recommends that EPA demonstrate that any new or revised regulatory measurement requirements are achievable on samples that represent the same level of analytical challenge as the matrix for which the regulation is intended, that is, don't publish a regulation without a method that works. (Ideally, this would be samples of the actual matrix to be monitored, as defined by the regulation.)	The Board voted to include an additional clarifying phrase to the recommendation.	<p>Recommendation remains open. Awaiting response from EMMC Policy Council.</p> <p>Assigned to PBMS subcommittee 12/17/99.</p>	HIGH

Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
15	7/28/97	ELAB recommends that EPA consider the following remaining issues: <ul style="list-style-type: none"> <li>• PB Measurement System <u>vs.</u> PB Method</li> <li>• Sample matrix</li> <li>• Method Validation</li> <li>• Method Compliance</li> <li>• Interlaboratory Comparability</li> <li>• Cost</li> <li>• Laboratory Client Relationship</li> </ul>		Recommendation has been superceded by final report of the PBMS subcommittee.  Assigned to PBMS subcommittee 12/17/99.	HIGH
16	7/28/97	ELAB recommends to NELAC that the initial approval of accrediting authorities should occur simultaneously		Completed. The NELAC Transition Committee has implemented this recommendation.	COMPLETED
17	7/28/97	ELAB recommends to NELAC that the first round of NELAC accreditation of laboratories by accrediting authorities should also occur simultaneously.		The NELAC Transition Committee has implemented this recommendation.	COMPLETED
18	7/28/97	ELAB recommends to NELAC that prior to the designation of approved proficiency test (PT) sample providers as required by Chapter 2, accredited labs should be allowed to continue using existing PT sample providers. However, in the interim, frequency of PT sample analysis as required by Chapter 2 must be met.		Completed. The NELAC Transition Committee has implemented this recommendation. The PT committee has modified the PT chapter to accommodate this recommendation	COMPLETED
19	7/28/97	ELAB recommends to NELAC that Chapter 6 be further defined regarding Accrediting Authority recognition of States to address the conflict of interest between public and private sector labs, with respect to a State laboratory conducting routine environmental testing analyses. Further definition will include the specific guidance to avoid conflict of interest for an above stated Accrediting Authority.	The NELAC Accrediting Authority Committee has implemented this recommendation. At NELAC IV further complaints were raised that the AA committee had not adequately addressed this issue.  See NELAC inputs to ELAB 6/30/99. Wording proposed for NELAC standards section 6.2.2.d responds to this concern.		COMPLETED

<b>Rec. #</b>	<b>Date of Rec</b>	<b>Recommendation</b>	<b>Notes</b>	<b>Action</b>	<b>ELAB Priority</b>
20	7/28/97	ELAB recommends to NELAC that the issue of primacy State laboratories in accrediting non-primacy State laboratories be referred to the Accrediting Authority Committee for further consideration.		Completed. The NELAC Accrediting Authority Committee has implemented this recommendation.	COMPLETED
21	7/28/97	ELAB strongly recommends to NELAC a vote for adoption of the Standards with modifications as specified and passed by ELAB motions on July 28, 1997.		Complete. NELAC adopted the standards.	COMPLETED
22	7/28/97	ELAB recommends that EPA Program Offices become more active in NELAC and promulgate regulations that are consistent with the NELAC standards as appropriate.	Nancy Wentworth, co-chair of the EMMC Panel on Laboratory Accreditation, discussed the steps that are being taken within the Agency to obtain a consensus opinion. In a meeting on March 9, 1999, the EPA Acting Deputy Administrator Peter Robertson agreed to pursue this.	Recommendation remains open. ELAB sent a letter to the EMMC Policy Council Co-Chairs noting that NELAC is awaiting critical input from EPA Program Offices through EMMC. ELAB encourages the Agency to provide that input in writing as soon as possible. Awaiting response from EMMC Policy Council.  Assigned to Regulatory Consistency subcommittee 12/17/99.	HIGH

Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
23	1/16/98	ELAB recommends to NELAC that an advisory appendix be written that addresses the issue of due process for laboratories. This appendix must address the rights, responsibilities, and obligations of the laboratories and accrediting authorities. The discussion should include, but not be limited to: <ul style="list-style-type: none"> <li>the right of the laboratory to see the audit report prior to action;</li> <li>the right of the laboratory to privacy during review;</li> <li>the right of the laboratory to appeal prior to suspension or revocation; and</li> <li>the right of the laboratory to confidentiality</li> </ul> .	Recommendation remains open. Awaiting response from AP committee.	Assigned to Z. English 12/17/99	HIGH
24	1/16/98	ELAB strongly recommends to NELAC that, during consideration of inclusion of sampling into NELAC standards, all stakeholders be represented.	Recommendation remains open. Awaiting response from Field Measurements ad hoc committee.	This recommendation relates to 41 and will addressed there.	INACTIVE
25	1/16/98	ELAB recommends that NELAC invite the Federal Partners Committee to make a report at NELAC IV (June 28, 1998) on their intention to 1) participate in NELAC; b) continue their own programs; and c) to serve as accrediting authorities.		B. Dutrow made presentation at NELAC IV plenary session on Federal Partners progress.	COMPLETED
26	1/16/98	ELAB recommends that EPA report on the Agency's action regarding PBMS and how it relates to the Quality Systems Chapter.		Awaiting response from EMMC Panel on Laboratory Accreditation.  Assigned to PBMS subcommittee 12/17/99	ACTIVE

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27A	7/1/98	ELAB recommends that EPA continue the Office of Water streamlining effort as an intermediate step to PBMS.	EPA has decided to develop a formal PBMS program for the Office of Water, separate from the OW streamlining.	Recommendation remains open. Awaiting response from EMMC Policy Council.  Assigned to PBMS subcommittee 12/17/99	MEDIUM
27B	7/1/98	ELAB recommends that a PBMS subcommittee be formed to develop and offer recommendations during NELAC IV [i] for integrating the development of NELAC and PBMS.	ELAB accepted on December 10, 1998, the report of the PBMS workgroup as a product of ELAB with the incorporation of previous findings and minor editorial changes. It was decided that a formal ELAB report will be sent by ELAB to EPA with an appropriate cover letter introducing the document and its issues. The PBMS working group report has been submitted to EPA's Acting Deputy Administrator Peter Robertson, during a meeting on March 9, 1999, at which time he agreed to address this issue with the EMMC Policy Council.	ELAB PBMS report on ELAB website.	COMPLETED
28	7/1/98	ELAB recommends that the NELAC Program Policy and Structure Committee review the structure of the AARB, consider expanding its charter to include an annual Management Systems Review of NELAP operations by an independent organization, include state members from the accrediting authorities, and address the timing of such reviews.		Recommendation remains open. Awaiting response from PPS committee.	MEDIUM

Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
29	7/1/98	ELAB recommends that EPA and the Department of Transportation address the inconsistencies between the EPA preservation requirements and the DOT shipping requirements.	ELAB sent a letter to both EPA and DOT requesting prompt resolution to this impasse. In a meeting on January 11, 1999, the EMMC Policy Council Co-chair Noreen Noonan agreed to pursue this issue.	Response received from DOT stating that the shipping requirements will not be changed. Awaiting response from EMMC Policy Council.  Mr. Friedman awaiting response from DOT (12/17/99).	HIGH
30	7/1/98	ELAB recommends that the proposed changes to the NELAC standards be adopted in the voting session scheduled for July 2, 1998.		Changes adopted.	COMPLETED
31	7/1/98	ELAB recommends that a third-party assessor workgroup be formed to evaluate minimum credentials for third-party assessors, both individuals and organizations. The workgroup will also review NELAC Chapter 6 to determine if the criteria are sufficient for States to evaluate third party assessors and make recommendations for revisions if not.	A work group has been formed chaired by Sandra Wroblewski and Bill Kavanagh.	Awaiting product from work group.  Assigned to Third Party Assessor Credentialing subcommittee 12/17/99.	HIGH
32	7/1/98	ELAB recommends that the ELAB Laboratory Assessment workgroup recommendations on checklists be forwarded to the NELAC On-site Assessment Committee for their consideration		Awaiting response from OA committee. Jerry Parr revised report for ELAB review and submission to NELAC. Report approved as final ELAB report for forwarding to NELAC and OA committee 4/29/99.  Review of ELAB Laboratory Assessment subcommittee report assigned to J. Parr 12/17/99.	HIGH



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33	7/1/98	ELAB recommends that the NELAC Accrediting Authority Committee further define and address conflict of interest between public and private sector laboratories.		Awaiting response from AA committee. This issue will be covered in recommendation 23.  Assigned to Z. English 12/17/99	ACTIVE
34	7/1/98	ELAB recommends that the NELAC Accreditation Process committee develop an advisory appendix that addresses the rights, responsibilities, and obligations of laboratories and accrediting authorities.		Awaiting response from AP committee. Issue will be covered in recommendation 23.  Assigned to Z. English 12/17/99	ACTIVE
35	1/14/99	ELAB recommends that NELAC reach out to laboratory associations through its web page by providing relevant links and sample standard operating procedures, case histories, sample quality manuals, and work sheets to assist small laboratories.			COMPLETED
36	1/14/99	ELAB will ensure a flow of information and guidance to the NELAC Committees by submitting significant information on to the NELAC Membership and Outreach Committee.		Recommendation remains open. Awaiting input from ELAB.  W. Hershey to inform M&O committee of FL and KS websites to assist small labs.	INACTIVE
37	1/14/99	ELAB recommends that NELAC continue to ensure that the NELAC standards contain only essentials to achieve the desired data quality; and, ELAB will make small laboratory issues a standing agenda item for future ELAB meetings.		Recommendation remains open. Awaiting input from ELAB. ELAB continues to include small laboratory issues on agendas.	INACTIVE

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38	1/14/99	ELAB recommends to NELAC that the NELAC Accreditation Process and Field Measurements Committees work together to develop a clear definition of critical terms (i.e., field laboratory, mobile laboratory, field measurement, and fixed laboratory) prior to defining the accreditation process for other than fixed laboratories; and, ELAB recommends to NELAC to exclude on-line monitors from its consideration.		Recommendation remains open. Awaiting response from AP and FM committees.  Assigned to A. Verstuyft, D. McClure 12/17/99.	HIGH
39	1/14/99	ELAB believes the current EPA proficiency testing program for water is unacceptably limited. ELAB recommends that EPA act quickly to broaden the availability of proficiency testing samples for matrices other than water (e.g. solid waste, air, tissue, etc.)		Recommendation remains open. Awaiting response from EMMC Policy Council  ELAB to request report from NELAC PT committee at NELAC VI.	HIGH
40	1/14/99	ELAB recommends to NELAC that a) the NELAC standards become effective and enforceable one year after adoption, and b) that for the first group of laboratories to be accredited under NELAC standards, the 1999 standards be used for compliance and that the related timelines for acceptance of applications be adjusted accordingly.		Recommendation remains open. Awaiting response from NELAC Board.	COMPLETED
41	12/10/98	ELAB recommends that work should forge on for field measurement standards. It was agreed that field sampling should be approached to determine the needs of stakeholders for standard-setting.  ELAB recommends that the Field Measurements ad hoc committee compile the variability associated with field sampling, collect field sampling protocols, review ISO guides for approaches, consult stakeholders, and re-visit the needs of EPA/OAR on the matter of field sampling.		Recommendation remains open. Awaiting response from FM committee.  Assigned to A. Verstuyft	HIGH

Rec. #	Date of Rec	Recommendation	Notes	Action	ELAB Priority
42	3/1/99	ELAB recommends to NELAC that the lab inspections be done according to NELAC standards and that the national database only track whether a lab is accredited and not have a separate category for interim status.	ELAB, at request of C. Batterton, NELAC BoD, considered the need for a new on-site related to the timing of the first Accrediting Authority recognitions in July 1999.	ELAB letter sent to NELAC, 3/25/99. Awaiting action by NELAC.  ELAB to request report from NELAP-recognized Accrediting Authorities by March-April 2000.	HIGH
43	12/17/99	Ensure consistency and coordination between USEPA regulations, guidance, and policies and the NELAC standards		Assigned to Regulatory Consistency subcommittee	
44	12/17/99	ELAB will address reconciliation & integration of ISO and NELAC standards		Assigned to NELAC-ISO Consistency subcommittee	
45	12/17/99	ELAB will review reporting information of NELAC national database			
46	12/17/99	ELAB will prepare “white paper” on advantages of national laboratory accreditation		Assigned to National Laboratory Accreditation Issues subcommittee	
47	12/17/99	ELAB to review process for developing PT acceptance limits under privatized PT program relative to regulatory requirements		Assigned to NELAC PT committee	
48	12/17/99	ELAB will review NELAC Fields of Testing with respect to EPA’s structure		Assigned to Scope of Accreditation subcommittee	
49	12/17/99	ELAB will review issues of QC samples, including field QC and matrix spikes		Assigned to QC Standards subcommittee	